

Applicants: Catherine Dulac and Richard Axel
Serial No.: 09/898,416
Filed: July 3, 2001
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REMARKS

Claims 96-99 are pending in the subject application. Claim 99 has been amended to reflect the election of Group III, claims 96-99, drawn to a nucleic acid encoding VN1, per the August 1, 2003 Communication in response to the July 1, 2003 Office Action. Support for amended claim 99 can be found in the specification at, *inter alia*, page 19, lines 3-7, page 37, lines 30 and 31 and Figure 4A. Applicants maintain that this Amendment raises no issue of new matter. Accordingly, upon entry of this Amendment, claims 96-99 will be pending and under examination.

Objection under 35 U.S.C. §132

The Examiner objected to the July 3, 2001 Amendment under 35 U.S.C. §132 as allegedly introducing new matter into the disclosure.

Specifically, the Examiner alleges that the addition on the paragraphs to page 19 constitutes the introduction of new matter in that the specification does not disclose the generic structure with the specific amino acid substitutions.

In response, applicants respectfully traverse.

Applicants maintain that the information added to page 19 of the specification via the July 3, 2001 Preliminary Amendment is fully supported by the originally filed specification, and can be found, *inter alia*, in the specification on page 15, lines 20-28, page 19, lines 2 and 3, page 37, lines 30 and 31, and Figure 4A. Applicants attach hereto, as **Exhibit A**, a marked-up copy of Figure 4A highlighting the regions of the disclosed vertebrate

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pheromone receptor amino acid sequences which serve as the basis for the generic structure. The specific amino acid substitutions are derived from those amino acid residues which differ among the disclosed amino acid sequences. Accordingly, applicants maintain that the July 3, 2001 Preliminary Amendment does not introduce new matter into the disclosure.

Rejection under 35 U.S.C. §101

The Examiner rejected claims 96-99 under 35 U.S.C. §101 because the claimed invention allegedly is not supported by either a substantial asserted utility or a well established utility.

Specifically, the Examiner alleges that the claimed nucleic acids encoding the polypeptides do not have a well established utility because G-protein coupled receptors with similar homology have different functions and the skilled artisan would have to determine the function of the receptor. The Examiner also alleges that even though the specification discloses an asserted utility of using the protein to provide insight into the chemical nature of pheromones, there is no nexus between the claimed protein and the therapeutics for innate behavior in humans.

In response, applicants respectfully traverse.

Applicants maintain that one skilled in the art would reasonably expect that the proteins encoded by the claimed isolated nucleic acids indeed function as pheromone receptors. Applicants direct the Examiner's attention to page 1, lines 30-33 of the specification which states, "[p]heromones activate the VNO [vomeronasal organ] and elicit a characteristic array of innate reproductive and social behaviors, along with dramatic

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neuroendocrine responses." Based on this information, applicants postulated that pheromone receptors would be restricted to neurons with the vomeronasal organ, and would not be observed in sensory neurons of the main olfactory epithelium or other non-neuronal cells. Based on these guidelines, applicants isolated seven proteins exhibiting properties consistent with those predicted for mammalian pheromone receptors (see page 41, line 32 to page 42, line 10 of the specification).

Accordingly, applicants maintain that the claimed isolated nucleic acids are reasonably expected to encode vertebrate pheromone receptors, and that these vertebrate pheromone receptors would have utility. For example, one possible substantial and well established utility for the encoded pheromone receptors is for screening compounds which can either activate or inhibit the activity of a pheromone receptor. It is not necessary for applicants to show conclusive proof of receptor activity, so long as reasonable expectation exists. Accordingly, applicants maintain that the claimed nucleic acids have utility, and that therefore, claims 96-99 satisfy the requirements of 35 U.S.C. §101.

The Examiner also rejected claims 96-99 under 35 U.S.C. §112, first paragraph, as allegedly not supported by either a substantial asserted utility or a well established utility, and thus not enabled. In response, applicants respectfully traverse for the reasons set forth above regarding the Examiner's rejection under 35 U.S.C. §101.

Rejections under 35 U.S.C. §112, First and Second Paragraphs

The Examiner also rejected claims 96-99 under 35 U.S.C. §112,

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second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regards as the invention.

Specifically, the Examiner states that claims 96-98 encompass consecutive amino acid sequences which are separated by multiple fragments with the term "or", and which are allegedly confusing because the fragments are of different size.

In response, applicants respectfully traverse.

Applicants maintain that claim 96, and dependent claims 97 and 98, are clear as written. Applicants note that the consecutive amino acid sequences recited in parts (a), (b) and (c) of claim 96 correspond to highly conserved regions in the disclosed pheromone receptors. When each of parts (a)-(c) of claim 96 is viewed in conjunction with the sequence listing recited, it is clear that each amino acid residue of the consecutive sequence is bounded by commas, and the amino acid or amino acids between the commas indicate the possible amino acids for that particular residue position. Thus, applicants maintain that claims 96-98 are not indefinite.

The Examiner also rejected claim 99 under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claim is drawn to non-elected groups.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that amended claim 99 provides an isolated nucleic acid of claim 96, wherein the nucleic acid encodes VN1 protein comprising consecutive amino acids having the sequence identical to the sequence set forth in

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SEQ. ID. NO:8. Accordingly, applicants maintain that the Examiner's rejection has been obviated.

The Examiner further rejected claims 96-98 under 35 U.S.C. §112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states that claims 96-98 encompass a subgenus of pheromone receptor with a specific amino acid description or substitution, and alleges that the specification does not disclose the claimed subgeneric pheromone receptor. Applicants understand the Examiner's use of the term "subgenus" to mean "genus" in this rejection.

In response, applicants respectfully traverse.

Applicants maintain that, as discussed earlier, the amino acid sequences recited in parts (a), (b) and (c) of claim 96 are fully disclosed in the specification as originally filed (see Exhibit A). Accordingly, the specification reasonably conveys to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Additionally, applicants disagree with the Examiner's position that *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* ("Lilly") mandates a finding of lack of written description, since the facts of that case differ fundamentally from those at hand.

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The Examiner further rejected claims 96-99 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

Specifically, the Examiner alleges that the subject matter is not described in the specification in such a way as to enable one skilled in the art to make and use the claimed invention.

In response, applicants respectfully traverse.

For the reasons discussed above, applicants maintain that one skilled in the art would reasonably expect that a protein encoded by a nucleic acid of claims 96-99 would be a vertebrate pheromone receptor. Applicants maintain that it would not require undue experimentation to make and use the claimed nucleic acids. Again, experimental proof of receptor activity for the encoded proteins is not needed so long as a reasonable expectation of such activity exists.

For the reasons above, applicants maintain that claims 96-99 satisfy the requirements of 35 U.S.C. §112, first and second paragraphs.

Priority under 35 U.S.C. §119(e) and §120

The Examiner acknowledges applicants' claim for domestic priority under 35 U.S.C. §119(e) and §120. However, the Examiner alleges that the continuing application upon which priority is claimed fails to provide adequate support under 35 U.S.C. §112 for the claimed invention.

In response, applicants again note the remarks above and maintain that the claimed invention is fully supported by the

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specification as originally filed.

Rejection under 35 U.S.C. §102(b)

The Examiner rejects claims 96-99 under 35 U.S.C. §102(b) as allegedly anticipated by Dulac, et al. (Cell, 1995).

Specifically, the Examiner alleges that Dulac, et al. discloses a nucleic acid encoding a pheromone receptor which is 100% identical to the claimed SEQ. ID. NO:8.

In response, applicants respectfully traverse.

Applicants note that the subject application claims the benefit of U.S. Serial No. 08/731,745 which was filed October 18, 1996. Dulac, et al. was published on October 20, 1995, less than one year prior to the filing of U.S. Serial No. 08/731,745. Accordingly, Dulac, et al. cannot be cited as a prior art reference against the subject application under 35 U.S.C. §102(b).

Accordingly, applicants maintain that claims 96-99 satisfy the requirements of 35 U.S.C. §102(b).

Summary

Based on the reasons set forth hereinabove, applicants maintain that pending claims 96-99 are in condition for allowance. Accordingly, allowance is respectfully requested.

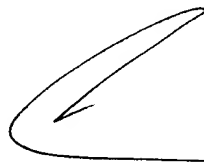
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is

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hereby given to charge the amount of such fee to Deposit Account
No. 03-3125.

If a telephone interview would be of assistance in advancing
prosecution of the subject application, applicants' undersigned
attorneys invite the Examiner to telephone them at the number
provided below.

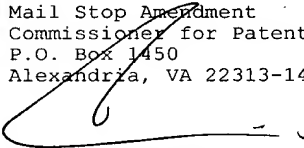
Respectfully submitted,



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